(g) the following sequence of ORF-5:

His-Leu-Ser-Gly-Thr-Ile-Cys-Gly-Ala-Leu-Cys-Leu-Phe-Ser-Tyr-His-Arg-Leu-Arg-Asp-Leu-Leu-Leu-Ile-Val-Thr-Arg-Ile-Val-Glu-Leu-Leu-Gly-Arg-Arg-Gly-Trp-Glu-Ala-Leu-Lys-Tyr-Trp-Trp-Asn-Leu-Leu-Gln-Tyr-Trp-Ser-Gln-Glu-Leu-Lys-Asn-Ser-Ala-Val-Ser-Leu-Leu-Asn-Ala-Thr-Ala-Ile-Ala-Val-Ala-Glu-Gly-Thr-Asp-Arg-Val-Ile-Glu-Val-Val-Gln-Gly-Ala-Cys-Arg-Ala-Ile-Arg-His-Ile-Pro-Arg-Arg-Ile-Arg-Gln-Gly-Leu-Glu-Arg-Ile-Leu-Leu-Ochre-Asp; and

(h) the following sequence of LTR:

Gly-Gly-Ser-Glu-Gly-Leu-Ile-His-Ser-Gln-Arg-Arg-Gln-Asp-Ile-Leu-Asp-Leu-Trp-Ile-Tyr-His-Thr-Gln-Gly-Tyr-Phe-Pro-Asp-Trp-Gln-Asn-Tyr-Thr-Pro-Gly-Pro-Gly-Val-Arg-Tyr-Pro-Leu-Thr-Phe-Gly-Trp-Cys-Tyr-Lys-Leu-Val-Pro-Val-Glu-Pro-Asp-Lys-Val-Glu-Glu-Ala-Asn-Lys-Gly-Glu-Asn-Thr-Ser-Leu-Leu-His-Pro-Val-Ser-Leu-His-Gly-Met-Asp-Asp-Pro-Glu-Arg-Glu-Val-Leu-Glu-Trp-Arg-Phe-Asp-Ser-Arg-Leu-Ala-Phe-His-His-Val-Ala-Arg-Glu-Leu-His-Pro-Glu-Tyr-Phe-Lys-Asn-Cys-*-His-Arg-Ala-Cys-Tyr-Lys-Gly-Leu-Ser-Ala-Gly-His-Phe-Pro-Gly-Arg-Arg-Gly-Leu-Gly-Gly-Thr-Gly-Glu-Trp-Arg-Ala-Leu-Arg-Trp-Trp-Ile-*-Ala-Ala-Ala-Phe-Cys-Leu-Tyr-Trp-Ala-Ser-Leu-Val-Arg-Pro-Asp-Leu-Ser-Leu-Gly-Ala-Leu-Trp-Leu-Thr-Arg-Glu-Pro-Thr-Ala-*-Ala-Ser-Ile-Lys-Leu-Ala-Leu-Ser-Ala-Ser-Ser-Ser-Val-Cys-Pro-Ser-Val-Val-*-Leu-Trp-*-Leu-Glu-Ile-Pro-Gln-Thr-Leu-Leu-Val-Ser-Val-Glu-Asn-Leu-*-Gln-Trp-Arg-Pro-Asn-Arg-Asp-Leu-Lys-Ala-Lys-Gly-Lys-Pro-Glu-Glu-Leu-Ser-Arg].

REMARKS

Applicants respectfully request reconsideration and reexamination of this application.

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Claims 12, 14, and 16 have been cancelled, without prejudice, for the sole purpose of advancing the prosecution of this case. Claims 11, 13, and 15 have been amended to delete the subject matter relating to peptides corresponding to ORF-3, ORF-5, and the LTR region of the HIV-1 genome. Applicants reserve the right to prosecute this subject matter in this or another application.

In addition, claims 11, 13, and 15 have been amended to recite amino acid sequences of ORF-R, ORF-Q, ORF-1, ORF-2, and ORF-4 of HIV-1 encoded by nucleic acids disclosed at page 12, line 29 through page 13, line 11 of the specification. The beginning of each peptide corresponds to the first methionine encoded by the disclosed nucleic acids, which is the beginning of translation. The end of each peptide corresponds exactly to the end of the nucleotide sequences disclosed at page 12, line 29 through page 13, line 11 of the specification. The amino sequences recited in the claims correspond to those given in Figures 4-12. As the foregoing amendments do not introduce new matter, it is respectfully requested that they be entered by the Examiner.

The Examiner stated that the oath or declaration was defective as it allegedly "does not identify the city and state or foreign country of residence of each inventor." See page 2 of Paper No. 6. Applicants respectfully disagree.

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Attached as Exhibit 1 is a copy of the original Declaration for this application, filed on March 5, 1993. The names of the inventors, the post office addresses of the inventors, and the country of citizenship for each of the inventors is given at page 2 of the Declaration. Accordingly, the Declaration is not defective.

The specification was objected to and claims 11-16 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to provide support for the claimed invention. Applicants respectfully traverse this ground for rejection.

The Examiner alleged that the specification was not enabling for claims to sequences of HIV-1, as the specification shows the cloning and sequence of LAV, a specific strain of HIV-1. See page 3, lines 21-24 of Paper No. 6.

HTLV-III, LAV, and ARV are all variants of the same virus, namely HIV-1. See Ratner, et al., "HTLV-III, LAV, ARV Are Variants Of Same AIDS Virus," Nature, 313, 636-637 (1985) (Exhibit 2); and col. 1, lines 22-38 of U.S. Patent No. 4,839,288 to Montagnier et al. (Exhibit 3). Accordingly, applicants' claims are enabled for sequences directed to HIV-1.

Continuing, the Examiner stated that while the claims are directed to "isolated antibody," "labeled antibody," "antibody which binds to an immunological complex," and "immunological complex which comprises an antibody," there is no description of isolating or labeling such antibodies. See page 2, lines 26-36 of Paper No. 6. Applicants respectfully disagree.

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The Examiner noted that techniques for isolation and labeling of antibodies were routine in the art at the time the claimed invention was made. See page 2, line 35 through page 3, line 1 of Paper No. 6. Continuing, however, the Examiner stated that there was no literal support for either isolated or labeled antibodies. See page 3, lines 1-2 of Paper No. 6.

It is not necessary for the specification to recite the word "isolated" to enable isolated antibodies. For subject matter to be enabled, it must be described such as to enable one of ordinary skill in the art at the time the claimed invention was made to practice the invention. See e.g., M.P.E.P. § 608.01(p). This standard is met by applicants' disclosure.

The specification teaches peptides of HIV, and that antibodies to these peptides are encompassed by the claimed invention. See e.g., page 15, line 30 through page 16, line 5. Techniques for producing and isolating such antibodies were well known in the art at the time the claimed invention was made. For example, Chang et al., "Production Of Monoclonal Antibodies in Serum Free Medium," Journal Of Immunological Methods, 39, 369-375, 370 (1980) (Exhibit 4), describes detection of antibody produced by hybridomas employing radioimmunoassays. Biosynthetic labeling of hybridoma products, and detection and characterization of immunoglobulin employing sodium dodecyl sulphate polyacrylamide gel electrophoresis (SDS-PAGE) are

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described by Eshhar et al., "Generation Of Hybridomas Secreting Murine Reaginic Antibodies Of Anti-DNP Specificity," The Journal of Immunology, 124, 775-780, 776 (1980) (Exhibit 5). The use of ion exchange chromatography to separate immunoglobulins from whole serum, and preparation of immunospecific (affinity-purified) antibody is described in Hurn et al., "Production of Reagent Antibodies," Methods In Enzymology, 70, 104-142, 126-132 (1980) (Exhibit 6). Fluorescein labeling of antibody globulins is described at pages 130-131; and peroxidase labeling of antibody globulins is described at pages 131-132 of Hurn et al. Various assays for isolating monoclonal antibodies are described by Galfre et al., "Preparation of Monoclonal Antibodies: Strategies and Procedures," Methods in Enzymology, 73, 3-46 (1981) (Exhibit 7). In particular, binding assays for detecting and isolating antibody are described at pages 22-29, and assays based on biological activity of antigen are described at pages 31-32 of Galfre et al.

As techniques for producing and isolating such antibodies were well known in the art at the time the claimed invention was made, this subject matter is not required to be described in the specification for enablement of the claims. See In re Strahilevitz, 212 U.S.P.Q. 561, 564 (C.C.P.A. 1982) ("[appellant] properly relies on literature citations to establish both the level of ordinary skill in the art and the fact that the techniques necessary to practice his invention were known in the art") (Exhibit 8).

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As the specification teaches that antibodies to the disclosed peptides are encompassed by the invention, and as techniques for producing and isolating antibodies were known in the art at the time the claimed invention was made, the specification is enabling for isolated antibodies.

The Examiner also stated that labeling of antibodies was not disclosed in the specification. Applicants note that labeling of antibodies is inherent in several different methods used for isolating antibodies. See e.g., Galfre et al. Thus, labeling of antibodies is inherent in applicants' teaching that antibodies against the disclosed peptides are encompassed by the present invention. Although applicants disagree with this ground for rejection of the claims, claims 12, 14, and 16, directed to labeled antibodies, have been cancelled solely for the purpose of advancing the prosecution of this application.

Continuing, the Examiner stated that the specification at pages 12 and 13 describes boundaries of the different ORF's which differ from the nucleotide sequences disclosed in the specification. See page 3, lines 5-8 of Paper No. 6.

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Claims 11, 13, and 15 have been amended to recite the boundaries of ORF-Q, ORF-R, ORF-1, ORF-2, and ORF-4 of HIV-1 as disclosed in the specification at page 12, line 35 through page 13, line 15.

Region of HIV-1	Location on Genome Given in Specification
ORF-Q	start 4478; end 5086
ORF-R	start 8249; end 8896
ORF-1	start 5029; end 5316
ORF-2	start 5273; end 5515
ORF-4	start 5519; end 5773

The beginning of the amino acid sequences of ORF-Q, ORF-R, ORF-1, ORF-2, and ORF-4 of HIV-1 recited in the amended claims correspond exactly to the first methionine encoded by the disclosed nucleic acids, which is the beginning of translation. The end of each peptide corresponds exactly to the end of the nucleotide sequences disclosed at page 12, line 29 through page 13, line 11 of the specification. The amino sequences recited in the claims correspond to those given in Figures 4-12.

As the specification is enabling for the claimed invention, the withdrawal of this ground for objection to the specification and rejection of the claims is respectfully requested.

Claims 11-16 were rejected under 35 U.S.C. § 101 because the claimed invention allegedly lacks patentable utility. Applicants respectfully traverse this ground for rejection.

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In the specification, applicants note that antibodies which bind with amino acid sequences encoded by ORF-Q, ORF-R, ORF-1, ORF-2, and ORF-4 of HIV-1 are useful as diagnostic reagents to detect the presence of HIV-1 in a biological sample. See page 16, lines 1-5. The Examiner disagreed with this statement of utility, in alleging that the peptides encoded by the ORFs may not be natural HIV proteins, and therefore would not be found in biological samples infected with HIV-1. See page 4, line 25 through page 5, line 9 of Paper No. 6.

While applicants disagree with the Examiner's analysis of the utility of the claimed invention as diagnostic reagents, it is courteously noted that the claimed invention is also useful for screening compositions for synthetic or natural peptides encoded by ORF-Q, ORF-R, ORF-1, ORF-2, and ORF-4 of HIV-1. Synthetic production of these peptides is described at, for example, page 15, lines 18-24 of the specification. Thus, the utility of the claimed antibodies is not limited to screening biological samples for the presence of ORF-Q, ORF-R, ORF-1, ORF-2, and ORF-4 of HIV-1. This utility is consistent with the statutory requirement of minimum utility for an invention. See M.P.E.P. § 608.01(p); and E.I. duPont de Nemours & Co. v. Berkley & Co., 205 U.S.P.Q. 1, 10 n.17 (8th Cir. 1980) ("[a] small degree of utility is sufficient. The claimed invention must only be capable of performing *some* beneficial function. An invention does not lack utility merely because the particular embodiment disclosed in the patent lacks perfection or performs crudely. . . . Nor is it essential that the invention accomplish

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all its intended functions . . . partial success being sufficient to demonstrate patentable utility . . .") (emphasis in original, citations omitted) (Exhibit 9). See also Envirotech Corp. v. Al George, Inc., 221 U.S.P.Q. 473, 480 (Fed. Cir. 1984) ("the defense of non-utility cannot be sustained without proof of total incapacity.") (Exhibit 10). As applicants' invention satisfies the "some" utility standard set forth above, the withdrawal of this ground for rejection is respectfully requested.

Applicants courteously submit that this application is now in condition for allowance. Reconsideration and reexamination of this application, and allowance of the pending claims at the Examiner's convenience, are respectfully requested.

If there are any fees due in connection with the filing of this Response, please charge such fees to our Deposit Account No. 06-0916. If a fee is required for an Extension of Time under 37 C.F.R. § 1.136 not accounted for above, such an Extension is requested and fee should also be charged to our Deposit Account.

Respectfully submitted,

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Dated: February 10, 1994

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